The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

PRIORITY DOCUMENT

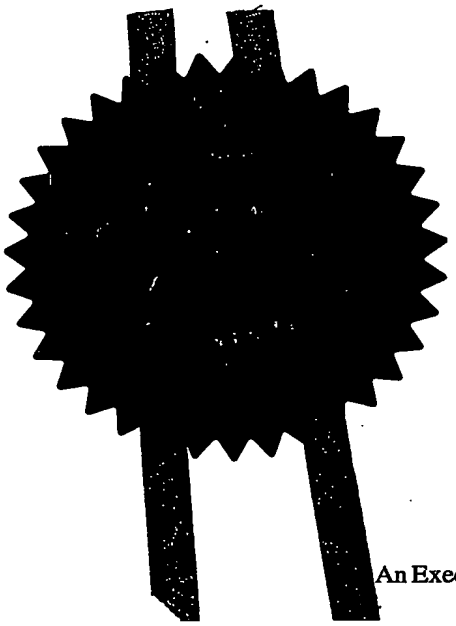
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



CERTIFIED COPY OF PRIORITY DOCUMENT

Signed

Dated 19 May 2003

Patents Form 1/77

Patents Act 1977
(Rule 16)

THE PATENT OFFICE
A
16 APR 2002
RECEIVED BY FAX

The Patent Office

16APR02 E711200-1 C04150
P01/7700 0.00-0208627.0

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference — 500

2. Patent application number *(The Patent Office will fill in this part)* — 0208627.0 — 16 APR 2002

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

IMPRINT PHARMACEUTICALS LIMITED
53 LANGTON ROAD
EAST MOLESEY
SURREY KT8 2HX
GB

Patents ADP number *(if you know it)* 7720352001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

NEEDLE

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

COHEN, ALAN NICOL
2 GROVE PLACE
TATSFIELD
Nr. WESTERHAM
KENT
TN16 2BB

Patents ADP number *(if you know it)* 6963557001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 17

Claim(s) 8 9

Abstract 1

Drawing(s) 7

please see Minute

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*

Request for preliminary examination and search *(Patents Form 9/77)*

Request for substantive examination *(Patents Form 10/77)*

Any other documents *(please specify)*

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 16-04-02

12. Name and daytime telephone number of person to contact in the United Kingdom A. N. Cohen 01959 577172

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

Improved Needle

The present invention relates to an improved needle design for use with injection devices such as hypodermic needles.

Hypodermic needles are constructed so that they comprise a hollow tube with an orifice at a sharpened end which penetrates the skin of the person being injected, normally the sharpened end of the needle is at an angle to the axis of the tube. In use the end of the needle penetrates the skin with the sharpened end cutting through the skin and subcutaneous layers. The size of the needle used depends on the characteristics of the fluid to be injected, with the larger diameter needles being used for larger volumes, higher viscosities, higher particulate size and concentration, and for fluids requiring either bigh flow rate or low shear or low pressure drop.

When using a hollow needle cannula for the conveyance of fluid particularly through the skin of a patient, a number of significant factors must be considered in the design of such cannula. For instance, the needle cannula should be sufficiently rigid and stiff so that it can effectively penetrate the skin of the patient without breaking or bending to such a degree so as to occlude the fluid path. In this regard, such needle cannulae are primarily made of metal so as to impart these desired stiffness characteristics. In addition to surface lubricity of the needle and the sharpness of the point, the outside diameter of the needle and its wall thickness play a factor in the penetration of the skin and the discomfiture attendant with such penetration. It has been suggested that reduction in the outside diameter and the wall thickness of the needle will provide greater ease in penetration of the skin of the patient and less pain. However, there is usually a tradeoff in merely reducing the outside diameter of the needle in order to achieve this desired ease of penetration. This tradeoff generally involves a narrowing or constriction of the inside diameter of the needle along with the reduction of the outside diameter of the needle. As a result, the flow capacity through the needle is impaired, especially if large flow rates or quantities of fluid are to be conveyed

through the needle. Furthermore, increasing the inside diameter by merely reducing the wall thickness of the needle will compromise the stiffness characteristics of the needle so that there will be a greater tendency to bend or break during its use.

These problems are exacerbated in hypodermic needles when unusually high viscosity or suspensions with high particulate levels or large particle sizes are used, or when unusually large volumes are used. Typical problems if the bore is too small include very slow injection, needle blockage and difficulty in applying sufficient pressure to the syringe plunger for delivery of fluid in an acceptable time.

A further problem arises with pain and trauma to the body tissues at the fluid injection site, due to distension caused by the bolus of larger volumes of injected fluid.

One solution to the fluid flow problems is to use a larger bore needle, but when larger bores are used to overcome the restrictions other problems arise due to pain and trauma of the tissue caused by the needle blade. Also, the larger needles are prone to forming a long cylindrical tissue core inside the bore of the needle during the needle entry into the body tissue. Such tissue cores are left at the injection site where they can necrotise and cause post injection pain for some days. Other needle types are known which have an atraumatic tip to reduce tissue cutting and coring, but these require an additional sharp cutting scalpel or hollow introducer to achieve entry through the skin.

Needles have been disclosed for reducing these problems in which the needles have a dispensing orifice at one end and a first portion distal from the dispensing orifice and a second portion proximal the dispensing orifice with the outside diameter of the second portion being smaller than the outside diameter of the first portion. US Patents 4335718, 4781691, 5792099 and 5951528 disclose such needles. In all these needles the dispensing orifice is at the sharpened end of the needle.

Another type of needle has multiple small holes along the axis of a 27-29 gauge needle for saline based therapies. This needle would not be suitable for the more viscous and particulate fluids mentioned above.

We have now devised an improved needle structure with reduces the above problems.

According to the invention there is provided a needle for use in an injector comprising (i) a tip, (ii) an elongate section adjacent the tip and (iii) a barrel section, there being an inner bore comprising a fluidic pathway, which inner bore is within the barrel and optionally extends down the elongate section and to the tip, there being one or more apertures fluidically connecting the said inner bore to the outside of the needle

The needle can be used with injection devices such as a hypodermic syringe and other injectors such as those described in patent applications PCT/GB99/02680 and PCT/GB00/03061. In the case of hypodermic injectors the fluid container is the barrel of the syringe and the fluid is injected by depressing a plunger as in conventional hypodermic syringes.

The tip, which is the first part to contact the skin when the needle is inserted into the skin can be a cutting blade, pointed or blunt. The tip is preferably designed for easy penetration of skin and/or tissue with minimum pain, damage or trauma.

Preferably the needle tip has an outside diameter of 0.2 to 1.5 mm. and the total needle length is 2 to 200mm. The needle tip diameter is preferably 1% to 100% of barrel diameter or the ratio of the tip diameter to the barrel diameter is between 1:1 and 1:10.

Preferably the ratio of the fluidic capacity of the barrel to the tube equivalent of the tip is between 1:1 to 1000:1.

Preferably the tip and or the rest of the needle are designed to minimise the friction and/or the force required and/or the pain of insertion into and or withdrawal from skin and tissue.

In one embodiment the tip is preferably angled to enable tiny cut to be made with a significant part of extension of the hole formed by needle being by stretch (more than 30%, 50%, 80%, 90%, 100%, 200% of the maximum aperture formed in skin in use is by reversible stretch, and less than 70%, 50%, 20%, 10% is by cutting). The tip can be hollow or solid, and can have a wall thickness greater than the barrel and/or elongate section.

In one embodiment the tip and/or other sections have one or more concave areas in between higher ridges, splines or rails running at least partly in parallel with the needle axis to minimise the surface contact area and/or pressure and/or penetration resistance and/or friction between needle and tissue. At least some of the ridges, splines or rails are preferably smooth, non cutting and generally prepared and radiused to promote low friction gliding through skin and tissue.

Preferably at least part of the elongate section has a gradient where the effective outer dimension increases gradually and/or in one or more steps from the tip until it joins the barrel section. The overall angle of step and the angle and/or radius of the leading and trailing edges of step is preferably chosen to ease entry with minimum force and/or pain/trauma of the skin/tissue being penetrated.

In a round needle if a tube is taken and then some of the external material ground away to make a slot/groove – the outside dimension which displaces the skin/tissue is reduced and this is what is meant by "effective outside dimension", as distinct from the perimeter which could include the outer circumference and the adjoining inner circumference of the bore. The "effective outside dimension" covers both the outside

diameter and/or the outer circumference e.g. which can be measured with a piece of string.

If the elongate section has an inner fluid carrying bore connecting fluidically to an aperture at tip, the outside shape can be of o, c, u, x, shape etc.

All or part of the barrel section can be inside the connection to the fluid container and made such that the majority of the greater than average bore of the needle does not penetrate the skin, but conducts the fluid to the point where the bore does penetrate the skin.

The elongate section can be may be hollow or solid and can have a wall thickness greater or smaller than the barrel.

The elongate section adjacent to the tip maintains or increases the size of a path in tissue formed initially by the tip, which can ease and direct the flow of fluid at least partly along or around the outside of the needle. Preferably the shape of the section is designed to reduce the frictional force of sliding against the adjacent tissue and is preferably is designed to reduce the fluidic friction of the flow going past the section in use.

When fluid pressure is applied, the elongate section forms all or part of a channel which nucleates or eases and directs the passage of at least part of the fluid flow with a smaller pressure drop than if the fluid were constrained inside the bore of the tube in that same location.

The barrel section preferably has a larger effective dimension than the elongate section, and in use, is connected directly or indirectly to a fluid holding and/or dispensing section, for example a syringe. In use the fluid passes from a fluid holding and or dispensing section to the barrel section and the barrel forms all of or part of the

fluidic connection between both one or more apertures and the liquid holding and or dispensing section.

The outer shape of the barrel preferably is designed to seal effectively to the skin and/or tissue when inserted therein and may be smooth and substantially round in cross-section to enable such easy sealing.

The barrel may join to and extend inside a luer lock or fluid holding part such as a syringe, and the part which extends inside may have an effective bore greater than the bore which enters the skin/tissue. The part of the barrel which remains outside the skin in use would normally have a fully enclosed bore.

Preferably the barrel has an outside diameter of 0.2 to 2.0mm. and the bore and/or outside diameter of the barrel and elongate section and /or tip varies e.g. the bore and/or outside diameter changes at the connection between the barrel and the fluid holding or dispensing part.

The apertures provide a fluidic pathway so that fluid moves from the inner bore to the outside of the needle when a pressure differential occurs. Such aperture(s) may be in one or more locations including the tip, the elongate section, the barrel, or at the junction of two sections.

The one or more apertures preferably extend in length more than 5 diameters of the adjacent tube and/or have an aspect ratio of more than 5:1 length to depth.

Preferably the included angle is less than 12° and the aperture(s) are positioned and angled to induce fluid to flow along and adjacent to the elongate section and are positioned and angled and radiused to reduce pain and catching, cutting or coring of skin or tissue in use.

Preferably at least part of at least one aperture is away from the tip and/or on a section of larger outer dimension than the tip.

Preferably the overall dimension of the aperture is larger than the tip outer dimension by a factor of 10%, 100%, 500%, or 1000%.

The one or more aperture(s) can be wholly or partly on the barrel which is larger than the elongate section.

The one or more aperture(s) can be longitudinal or radial, round or elongate or a slot or a groove, and can penetrate through one wall or through both walls of the tube. When the needle is to be used for particulate fluids, in order to prevent blockage of needle, the part of the barrel where the fluid first meets the constriction at the opening of the barrel will preferably have an aperture of smaller inner dimension than the bore of the barrel and be of inverted funnel shape whereby in use the first bore encountered by the fluid is smaller than the bore of the barrel.

Preferably at least one aperture is spaced apart from the tip and is located substantially where the there is a step change in the outside diameter e.g. it is located on the gradient where the elongate section joins the barrel it is located on the elongate section and optionally can or cannot not adjoin the tip

Preferably the aperture is greater than 1-10mm long

In use, as the end of the needle penetrates the skin and tissue, the skin forms a temporary substantially fluid tight seal over the aperture so the fluid passing down the barrel is constrained to pass down the barrel. Under pressure from the injector the fluid then forms a bolus around the aperture and enters the tissue as in conventional needles. In practice this means that part of the fluidic conduit is defined by the tissue

itself so that the effective bore of the conduit is wider/larger than the bore entering through the skin.

The aperture may be any shape and is preferably in the form of a groove or slot in the needle and preferably encompasses up to 1 to 80% of the circumference of the bore of the conduit e.g. up to 10%, 30%, 50%, 70%. In use, as the upper layer of skin is strong and elastic and seals tightly to the smooth upper barrel, the aperture is designed to be below the skin surface and the skin forms a seal over the groove, or slot and the groove or slot forms an opening beneath the skin which minimises leakage of fluid being injected during injection and on withdrawal of needle.

The aperture may be parallel or perpendicular or angled to the axis of the needle.

Preferably the aspect ratio of the outer tube diameter to slot length is greater than or in range 1: 2 to 1:50 e.g. 1 to 2; 1 to 4; 1 to 10; 1 to 20 or 1 to 50.

Preferably the ratio of slot length to elongate section length is greater than or in range 1:1.5 to 1:10 e.g. 1 to 2; 1 to 3; 1 to 4 or 1 to 10 or 1:20.

In another embodiment of the invention the aperture is deformable i.e. under pressure from within the bore the aperture opens up so that it gets wider in use.

The end of the aperture nearest the tip can be closed or it can be open, in the latter case, when the aperture is a groove or slot the groove or slot can go to the tip of the needle or it can be distant from the tip of the needle.

A completely or partly solid needle can be used in which a groove is formed in the side of the solid part of the needle, down which groove the fluid to be injected can flow. In this embodiment the groove can terminate a distance from the tip end of the needle

which penetrates the skin so that the tip of the needle can form a skin penetration section or the groove can reach to the end of the needle.

Alternatively the needle can comprise a hollow needle with part of the needle axially removed e.g. by cutting or grinding.

The groove can be formed in a solid or hollow needle by forming or deforming the tube e.g. into a "u", "c", "v", "y" or "x" shape or by grinding away a section of the needle.

In use the tip enters the skin first and the elongate section penetrates the skin and displaces tissue along its length and forms a guide path for the tip. The tip enters the tissue and the fluid is injected and enters the tissue along the length of the aperture.

The elongate section in use, can be hollow or solid, and facilitates and guides nucleation of fluidic path at least partially in a forward direction towards the tip which is followed and then expanded when the fluid is applied from the aperture under pressure. The cross sectional outer shape of the elongate section is designed to minimise trauma and can also facilitate the fluid pathway. It can have 0, 1, 2, 3 or 4 axes of symmetry to form corresponding displacement of tissue along its length e.g. the cross section can be an ellipse, rectangle, star, diamond etc. The elongate section can be straight or tapered, can be longer than 2-3mm, preferably 2-20mm, can be a single piece or 2 pieces joined, can be swaged or drawn , can be solid or hollow.

The needle structure of the present invention can be used with a balloon catheter which comprises a deformable or elastic sheath which has an aperture or apertures in it and which fits around or encases the needle. The balloon catheter can be used with a hollow needle so that the aperture or apertures connect with the conduit or it can be used with a hollow grooved needle so that the aperture or apertures connect with the grooved path.

It is a feature of the invention that it enables a needle to be used with a shorter confined bore, i.e. the part of the needle which is in the form of a complete tube is shorter. It also allows use of a larger bore for a proportionally greater part of the needles entire length. As much of the pressure drop is the friction of the fluid in the confined bore of the needle, the shorter the confined bore and the greater the proportional length of the larger bore, the less pressure drop, so faster injections and less pressure required. For drugs containing particulates, the needle is also likely to block, so a shorter bore means less pressure drop and less risk of blockage. Once the needle of the invention is through the skin surface, there is a liquid-tight seal where the needle is in the tight upper layers of the skin. Because the tissue below the skin surface is much more pliable and it easily deforms under even small fluid pressure, if at least part the needle below skin is only a "partial bore" e.g. semi-bore or other partial smaller shapes, then it is much easier for the fluid to get along the track defined by the needle, and the fluid contacts more strata/channels/fissures in the tissue so it is easier for the fluid to disperse into the greater number/area of strata.

Because the fluid is spread over more tissue strata/area, it is likely there is less local stretch hence less pain/trauma even for the faster injection rates which the new needle creates and, because there is easier dispersion of fluid and lower back-pressure of fluid in the tissue, there is less chance of blistering and/or back-leakage of fluid out of the hole in the skin

Overall the needle design of the present invention enables "smaller" needles to achieve the same fluidic carrying capacity as larger conventional needles at lower pressure and with less pain/trauma/leakage than a conventional hypodermic or autoinjector.

The smaller needle can be a shorter needle and/or have a smaller cross-section or can be a needle tapering along its length either gradually, or in "steps" of smaller diameter.

For many uses the needle has a length of 2 to 200mm.

In use there is preferably a minimum of cutting and displacement by the needle itself in relation to the fluidic capacity and there is a minimum total dimension (length and or area) of sharp cutting edges and/or points, and minimum level of sharpness in relation to the size and fluidic capacity

In use the small hole formed in skin and tissue by the tip is smoothly extended along the tip and elongate section with minimum of sharp edges or sharp changes in direction to catch or snag tissue

The needle can comprise at least one separate component made of one or more different materials and which the separate parts are joined together

The needle can be made by process steps comprising forming a step in the diameter of a needle tube, closing the tip of needle, forming a primary angle onto tip, processing by mechanical or chemical means to increase the radii of the edges of the tip and aperture, forming step to make final tip dimensions. Preferably the process includes the steps of providing surface texture to reduce friction and/or retain lubricant at surface and includes increasing the edge radii of the tip.

The needle can be used with any injection device such as a syringe, pen, autoinjector, syringe driver, tissue/fluid extraction device and the length of the needle is chosen for the application of the needle. Examples of use are to add or remove substance including intradermal, sub-cutaneous, intra-muscular, intra-venous, into bone, into joint, into eye, into any organ, and for keyhole surgery. The needle can also be used to add or remove substance for medicinal or diagnostic or other purposes for human or animal or other applications

When used with an autoinjector, there is preferably a guide which fits to the autoinjector and which fits round the needle and which directly or indirectly helps the needle run straight along its axis with minimum wobble by restricting the axial or lateral movement of needle and/or liquid holding elements attached to needle. The guide can optionally fit around the needle directly, or it can also guide the needle indirectly by guiding the item to which the needle is fixed, e.g. the drug holding syringe or cartridge. This enables easier needle entry and reduces the pain, trauma and bleeding, which is often problem with autoinjectors especially with large needles. Preferably the guide restricts needle transaxial or lateral movement in use to below 1-10° e.g. 0.01-1° and 1-3mm e.g. 0.1-1mm. The guide is preferably of low friction material and may be a simple hollow cylinder or have one or more sprung elements to maintain close sliding tolerance while allowing for variations in manufactured size with minimum frictions. The guide has minimum contact with moving needle-holding element to reduce friction

The needle of the present invention enables a lower pressure/time profile compared to standard hypodermic needles and enables higher viscosity, higher volume, greater level and/or size of particulates.

The needle of the invention can provide easy entry into skin and or tissue with low entry force, low trauma and low leakage i.e. it can combine minimal cut/tear with gentle stretch to increase path in skin/tissue). It has high fluidic capacity (i.e. can carry high viscosity/volume/particulates/flow rate; the key determinant is diameter and length of bore, as the pressure drop is proportional length/(diameter^2), where d is the diameter of the bore, slot itself has little effect on pressure drop unless it is extremely narrow; however, a small slot is much more likely to be blocked by particulates). The needle also is easy to manufacture at low cost.

The needle including one or more of hub, barrel, elongate, tip and point may comprise one or more components joined, and may be made from one or more materials.

The invention is illustrated in the accompanying drawings in which :-

Fig. 1 shows an embodiment of the invention

Figs. 2, 3, 4, 5 and 6 show different embodiments of the invention

Fig. 7 shows cross sectional profiles of grooves which can be used with the needle of fig. 2

Fig. 8 shows an embodiment of the invention using a stepped needle

Figs. 9 show other embodiments and

Fig. 10 shows a needle with the gradient away from the heel of the aperture and

Fig. 11 shows an end view of a needle guide.

Referring to fig. 1 a needle has a tip (7), a hub (1) connected to a fluid reservoir and dispenser such as a hypodermic syringe, barrel section (6) connected to the hub and syringe and an elongate section (2) which has an inner bore (3) which is a conduit and which has an outer surface (4). There is an aperture (5) which connects outer surface (4) to the inner bore (3).

In use the needle penetrates the skin (8) which seals the aperture as it passes through it. When the needle has penetrated into the tissue (9) the fluid is injected down inner bore (3) and is injected into tissue (9) through aperture (5) where it forms bolus (10). As can be seen the size of the bolus is much larger than which would be formed by a conventional needle of the same diameter.

Referring to fig. 2 this shows a barrel (6) with a bore which enters the skin and an elongate part (12) which is solid along its length and which has a groove (13) formed in it so that the cross section view of the needle is shown in fig. 2a. In use the needle penetrates the skin and tissue so the barrel end/aperture and groove are below the surface and the fluid is then injected down the groove (13) into the tissue.

Fig. 7 shows various shapes of grooves

Referring to figs. 3a and 3b, these show a plan view and side view of an embodiment in which a needle (16), which can be made of metal or a suitable plastics material, has a slot (17) formed in it, (the slot (17) may extend further than shown). The needle has a tip (18) which can be metal or made of a suitable plastics material and can be blunt or sharp. In use the needle tip (18) penetrates the skin as described above and liquid to be injected passes under pressure down needle (16) and out through slot (17). The slot (17) can be made deformable so that it expands under pressure.

Referring to figs. 4a and 4b these show a plan view and a side view of a further embodiment of the invention and in which there is a long slot or opening (20) in needle (23). The needle can be mounted through mounting (22) into a luer or other connector or can be permanently attached to a syringe.

Referring to figs. 5a and 5b these illustrate the use of a balloon catheter which comprises a deformable or elastic sheath which has an aperture (27) in it which sheath fits around or encases the needle (25) there is a solid or hollow elongate section (28) at its tip. In use the tip and all or part of the elongate section enters the skin and tissue and facilitates and guides a path for the needle encased by the balloon catheter to follow. The embodiment of fig. 5a can also have an even larger bore in the hub.

Referring to fig. 6 there is an off centre solid needle (30) mounted in a needle mounting (31) into a luer or other connector or it can be permanently attached to a syringe. There is a fluid opening (32) which connects to syringe. In use the needle (30) penetrates the skin and tissue and forms a path through the tissue, when fluid is supplied under pressure to opening (32), which is connected to the fluid chamber of a syringe, the path formed by needle (30) facilitates and guides nucleation of fluidic path which is followed and then expanded by the fluid.

Referring to fig. 8a the syringe body is shown at (33) and the skin is (34). The barrel section has first large bore section (35) and, optionally it can have several reducing

sections or a long taper and a second smaller bore section (36). The aperture is formed by cutting away portion (37) of section (36) on or adjacent to the taper or step (40). There is a hollow or solid penetration end (38). In use the end (38) penetrates the skin (34) until the aperture (37) is below the surface and the fluid is then injected and the fluid forms the elongated bolus shown at (39).

Referring to fig 8b, this shows a single step or taper from a large bore barrel to the elongate section

Referring to fig 8c, this shows another embodiment in which at least one aperture is positioned entirely on the elongate section

Referring to figure 9a there is a syringe (40) connected to barrel section (44), elongate section (41) and tip (43). There is a portion of the elongate section (42) cut away to form a slot shaped aperture so the elongate section is tapered. There is a bore down the inside of the barrel section and elongate section which connects the syringe to the aperture (42).

Fig. 9b shows a side view and a top view of the needle where the elongate section is a long taper which tapers to below 50% of the barrel and/or elongate outer dimension and the needle taper continues into the tip and end point.

Referring to fig. 9c this embodiment shows a concave curvature section (51) on the face of tip and/or on other parts of needle and/or ridges, rails or splines the depth of concave is 1-80% of adjacent needle outer diameter; there are rails (52) to the bevel point. Figs. 9d and 9e show two bevel points and four bevel points respectively when viewed from the tip with concave sections (51).

In use the needle penetrates the skin to location (41) and the syringe operated to inject fluid. As in the other embodiments the skin seals the aperture as it passes through it.

When the needle has penetrated into the tissue the fluid is injected down inner bore and is injected into tissue through aperture (42).

Referring to fig. 10 this shows a needle in which at least part of the gradient (53) is positioned away from the heel of the aperture at the syringe end of the aperture, i.e. opposite end of aperture from the tip.

Referring to fig. 11 there is an outer guide (60) of the autoinjector , the moving drug holding section (62) and needle (61). The needle guides comprise sprung sections (63) which hold the needle in position and minimise wobble and lateral movement of the needle in use.

The use of a needle of the invention is described in the example.

Example

A needle as shown in fig. 8b of the accompanying drawings with tip and elongate section 26 gauge and barrel of 21 gauge of was made and its performance compared with control needles comprising standard Beckton Dickinson Microlance (Registered Trade Mark) needles of 21 gauge and 26. The tests consisted of 1) applying fluids of different viscosities through the needles from a 2ml standard glass syringe using constant force/weight of 1kg applied to the syringe plunger. 2) Needle penetration-force tests through standard elastomer tape 0.4mm thick.

Measurements taken included fluid flow data and time for constant volume of fluid to inject using new needles vs. conventional needles of same length and comparable size and fluidic capacity, insertion force data of new needles vs. conventional needles of comparable size and fluidic capacity and pain score data of new needles vs. conventional needles of comparable size and fluidic capacity.

The results showed that the needle 8a penetrated the film or skin with force and/or pain comparable to the standard 26 gauge needle. However, the flow rate or fluid carrying capacity of the needle 8a was comparable to the 21 gauge standard needle.

5

Claims

1. A needle for use in an injector comprising (i) a tip, (ii) an elongate section adjacent the tip and (iii) a barrel section, there being an inner bore comprising a fluidic pathway, which inner bore is within the barrel and optionally extends down the elongate section and to the tip, there being one or more apertures fluidically connecting the said inner bore to the outside of the needle

2. A needle as claimed in claim 1 in which the tip has a cutting end with one or more bevels sharpened into blades.

3. A needle as claimed in any one of claims 1 or 2 in which the needle has a non cutting atraumatic tip, smooth and with a conical or curved tip with substantially curved radii at the foremost point so that, in use it substantially parts tissue without cutting.

4. A needle as claimed in any one of claims 1 to 3 in which the tip is a sharp or non sharp blade of cross sectional area smaller than that of the elongate section, the latter in use facilitates and guides nucleation of fluidic path from the channel or aperture at least partially in a forward direction towards the tip and which is followed and then expanded when the fluid is applied from the aperture under pressure.

5. A needle as claimed in any one of claims 1 to 4 in which the needle tip has an outside diameter of 0.2 to 1.5 mm.

6. A needle as claimed in any one of the preceding claims in which the needle length is 2 to 200mm.

7. A needle as claimed in any one of the preceding claims in which the needle tip diameter is 1% to 100% of barrel diameter

8. A needle as claimed in any one of the preceding claims in which the ratio of the tip diameter to the barrel diameter is between 1:1 and 1:10

9. A needle as claimed in any one of the preceding claims in which the ratio of the fluidic capacity of the barrel to the tube equivalent of the tip is between 1:1 to 1000:1.

10. A needle as claimed in any one of claims 1 to 9 in which at least part of the elongate section has a gradient where the effective outside dimension is made to increase gradually and/or in one or more steps from the tip until it joins the barrel section

11. A needle as claimed in claim 6 in which the overall angle of one or more step/gradient and the angle and/or radius of the leading and trailing edges of step/gradient is chosen to ease entry with minimum force and/or pain/trauma of the skin/tissue being penetrated.

12. A needle as claimed in any one of claims 1 to 11 in which the elongate section has a fluid carrying bore or channel connecting fluidically to an aperture at tip and the bore or channel is of o, c, u, x, shape etc.

13. A needle as claimed in any one of claims 1 to 12 in which at least part of at least one aperture is spaced away from the tip.

14. A needle as claimed in any one of the preceding claims in which the barrel has an outside diameter of 0.2 to 2.0 mm.

15. A needle as claimed in any one of the preceding claims in which the bore and/or outside diameter of the barrel and elongate section and /or tip varies.

16. A needle as claimed in claim 15 in which the bore and/or outside diameter changes at the connection between the barrel and the fluid holding or dispensing part.

17. A needle as claimed in any one of claims 1 to 16 in which all or part of the barrel section is inside the connection to a fluid container and made such that the majority of the greater than average bore of the needle does not penetrate the skin, but conducts the fluid to the point where the bore does penetrate the skin.

18. A needle as claimed in any one of claims 1 to 17 in which the elongate section is hollow or solid and has a wall thickness greater or lesser than the barrel

19. A needle as claimed in any one of claims 1 to 18 in which, in use, the elongate section maintains or increases the size of a path in tissue formed initially by the tip, and eases and directs the flow of fluid at least partly along or around the outside of the needle at least partly in a forward direction towards the tip..

20. A needle as claimed in any one of claims 1 to 19 in which, in use, when fluid pressure is applied, the elongate section forms all or part of a channel which nucleates or eases and directs the passage of at least part of the fluid flow with a smaller pressure drop than if the fluid were constrained inside the bore of the tube in that same location.

21. A needle as claimed in any one of claims 1 to 20 in which the aperture encompasses 10% to 80% of the circumference of the bore of the barrel.

22. A needle as claimed in any one of claims 1 to 21 in which the aperture is in the form of a groove or slot.

23. A needle as claimed in any one of claims 1 to 22 in which the one or more apertures extend in length more than 5 diameters of the adjacent tube and have an aspect ratio of more than 5:1 length to depth.

24. A needle as claimed in any one of claims 1 to 23 in which the one or more apertures have an included angle of less than 12° and the aperture(s) are positioned and angled to induce fluid to flow along and adjacent to the elongate section and are positioned and angled and radiused to reduce catching, cutting or coring of skin or tissue in use.

25. A needle as claimed in any one of claims 1 to 24 in which at least part of at least one aperture is away from the tip and/or on a section of larger outer dimension than the tip.

26. A needle as claimed in any one of claims 1 to 25 in which the overall dimension of at least one aperture is larger than the tip outer dimension by a factor within the range of 10%, 100%, 500% and 1000%.

27. A needle as claimed in any one of claims 1 to 25 in which the one or more aperture(s) are longitudinal or radial, round or elongate or a slot or a groove, and can penetrate through one wall or through both walls of the tube.

28. A needle as claimed in any one of the preceding claims in which the aperture is in the form of a slot which is deformable and expands under pressure in use

29. A needle as claimed in any one of the preceding claims in which at least part of at least one aperture is spaced apart from the tip and is located substantially where the there is a gradient or step change in the outside diameter.

30. A needle as claimed in claim 29 in which one or more apertures is on or adjacent to a gradient or step change in outer dimension other than the tip.

31. A needle as claimed in any one of the preceding claims in which at least part of gradient is positioned away from the heel of aperture at syringe end of aperture i.e. on opposite side of aperture from the tip.

32. A needle as claimed in any one of claims 1 to 31 in which at least part of at least one aperture is located on the gradient where the elongate section joins the barrel.

33. A needle as claimed in any one of claims 1 to 31 in which at least part of at least one aperture is located on the elongate section and optionally can or cannot not adjoin the tip.

34. A needle as claimed in any one of the preceding claims in which the aperture is greater than 1-10mm long

35. A needle as claimed in any one of claims 1 to 34 in which the part of the barrel where the fluid first meets the constriction at the opening of the barrel has an aperture of smaller inner dimension than the bore of the barrel and is of inverted funnel shape whereby in use the first bore encountered by the fluid is smaller than the bore of the barrel.

36. A needle as claimed in any one of claims 1 to 35 in which the aperture has an aspect ratio of width to length in the range 1:2 to 1: 500

37. A needle as claimed in any one of claims 1 to 36 in which the aperture has an aspect ratio of width to length greater than 1:10

38. A needle as claimed in any one of claims 1 to 37 in which the aspect ratio of the inner bore diameter to slot length is greater than or in range of 1:2 to 1:50

39. A needle as claimed in any one of claims 1 to 38 in which the aspect ratio of the inner bore diameter to slot length is greater than 1: 5.

40. A needle as claimed in any one of claims 1 to 39 in which the aspect ratio of the outer tube diameter to slot length is greater than or in range 1: 2 to 1:50

41. A needle as claimed in any one of claims 1 to 40 in which the aspect ratio of the outer tube diameter to slot length is greater than 1 to 4.

42. A needle as claimed in any one of claims 1 to 41 in which the ratio of slot length to overall needle length is greater than or in range 1:1.5 to 1:10

43. A needle as claimed in any one of the preceding claims in which the end of the aperture nearest the tip is open.

44. A needle as claimed in claim 42 in which the barrel enters the skin and the elongate section is solid and the aperture at the end of the barrel adjoins to the groove or slot and the groove or slot goes to the tip end of the needle

45. A needle as claimed in any one of claims 1 to 43, in which the end of the channel or bore nearest the tip is closed.

46. A needle as claimed in claim 45 in which the needle is a solid needle and the aperture is a groove or slot and the groove or slot terminates at a position spaced apart from the tip.

47. A needle as claimed in any one of the preceding claims which incorporates a balloon catheter which comprises a deformable or elastic sheath which has an aperture or apertures in it, which sheath fits around or encases the needle and in use the aperture or apertures in the sheath are below the skin and connect with the aperture in the needle.

48. A needle as claimed in any one of the preceding claims in which the needle has a length of 2 to 200mm.

49. A needle as claimed in any one of the preceding claims in which there is overall a minimum of cutting and displacement by the needle itself in relation to the fluidic capacity.

50. A needle as claimed in any one of the preceding claims in which there is a minimum total dimension (length and or area) of sharp cutting edges and/or points, and minimum level of sharpness in relation to the size and fluidic capacity

51. A needle as claimed in any one of the preceding claims in which in use the small aperture formed in skin and tissue by the tip is smoothly extended along the tip and elongate section with minimum of sharp edges or sharp changes in direction to catch or snag tissue

52. A needle as claimed in any one of the preceding claims which comprises at least one separate component made of one or more different materials and which the separate parts are joined together

53. A needle as claimed in any one of the preceding claims which is made by process steps comprising forming a step in the diameter of a needle tube, closing the tip of needle, forming a primary angle onto tip, processing by mechanical or chemical means

to increase the radii of the edges of the tip and aperture, forming step to make final tip dimensions

54. A process of making a needle which needle is as claimed in any one of the preceding claims which process includes the steps of providing surface texture to reduce friction and/or retain lubricant at surface.

55. A process of making a needle which needle is as claimed in any one of the preceding claims which process includes increasing the edge radii of the tip and/or heel and/or edges of one or more apertures.

56. An injection device incorporating a needle as claimed in any one of the preceding claims

57. A needle and injection device as claimed in claim 56 in which the injection device comprises a syringe, pen, autoinjector, syringe driver, tissue/fluid extraction device.

58. A needle as claimed in any one of the preceding claims in which the length of the needle is chosen for the application of the needle.

59. A needle as claimed in claim 58 in which the applications are selected from the use of the needle to add or remove substance including intradermal, sub-cutaneous, intra-muscular, intra-venous, into bone, into joint, into eye, into any organ, and for keyhole surgery.

60. The use of a needle as claimed in any one of the preceding claims to add or remove substance for medicinal or diagnostic or other purposes for human or animal or other applications

61. A needle as claimed in any one of the preceding claims in which there is a concave curvature on the face of tip and/or on other parts of needle and/or with ridges, rails or splines to reduce force/friction of needle against skin/tissue and/or coring of tissue into aperture.

62. A needle as claimed in claim 61 in which the depth of the concave section is 1-80% of adjacent needle outer diameter.

63. A needle as claimed in claim 61 in which the depth of the concave section is 1-80% of adjacent needle diameter and the concave section is radiused to 1-200% of outside diameter

64. A needle as claimed in any one of the preceding claims in which there is a needle guide surrounding the needle which restricts the axial or lateral movement of needle and/or liquid holding elements attached to needle.

65. A needle as claimed in claim 64 in which the guide restricts needle transaxial or lateral movement in use to below 0.01-1°; 1-10°; 0.1-1mm; 1-3mm.

66. A needle as claimed in claim 64 or 65 in which the guide has one or more sprung elements to maintain tight tolerance while allowing for variations in manufactured size and guide has minimum contact with moving needle-holding element to reduce friction.

67. A needle as claimed in any one of the preceding claims combined with an autoinjector or pen.

68. A needle as claimed in claim 67 in which the autoinjector or pen has high pressure delivery of fluid above 10,20, 50, 100 or 200 bar.

Abstract

An improved needle for use with injectors such hypodermic needles has an aperture in its side so that, after the needle penetrates the tissue, the injected fluid is injected via the aperture.

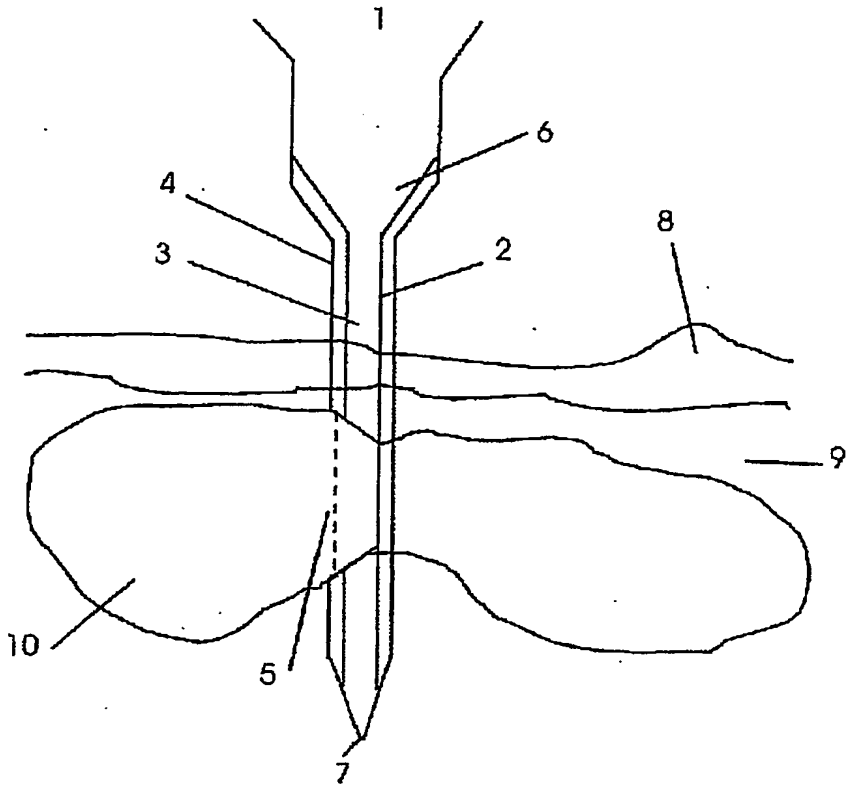


Fig. 1

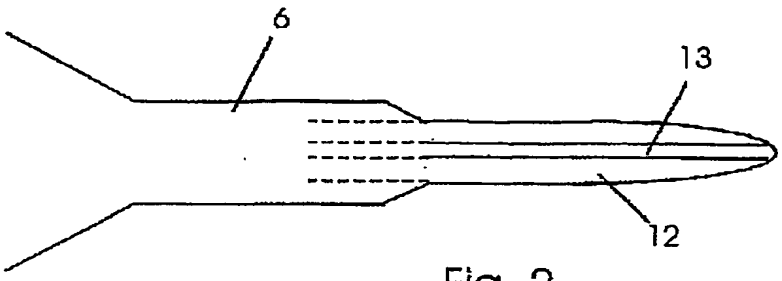


Fig. 2

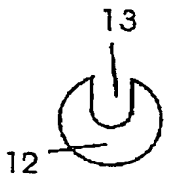


Fig. 2a

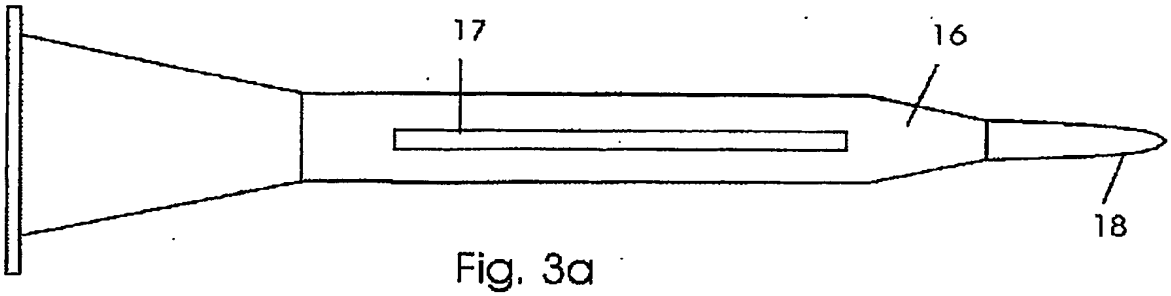


Fig. 3a

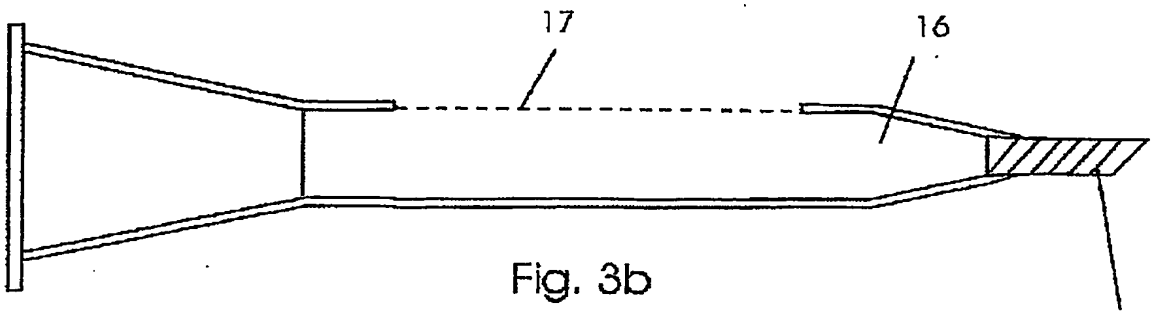


Fig. 3b

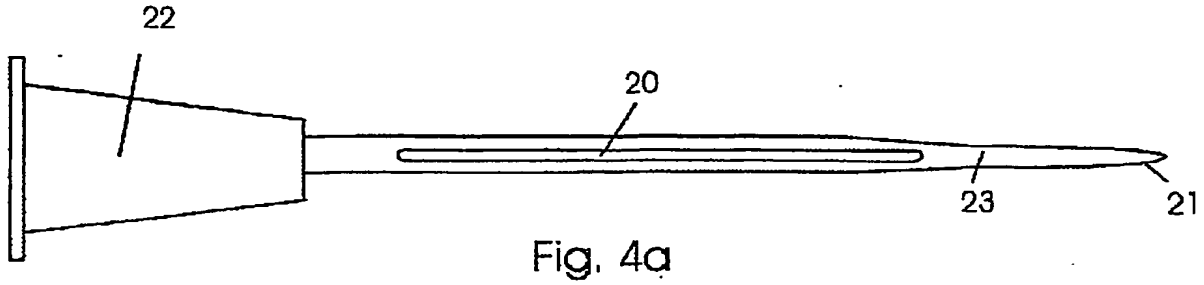


Fig. 4a

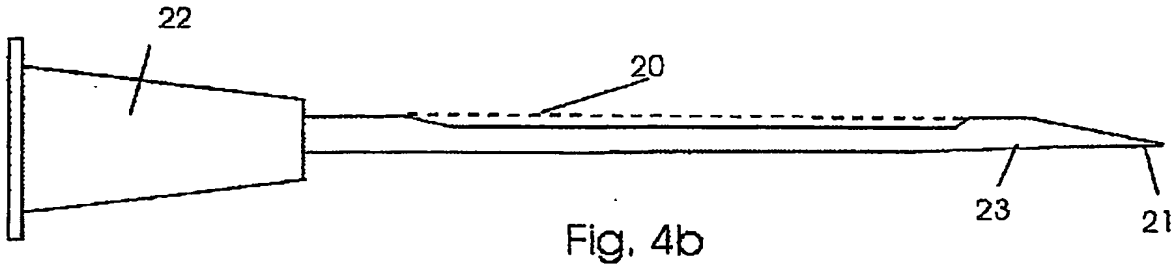


Fig. 4b

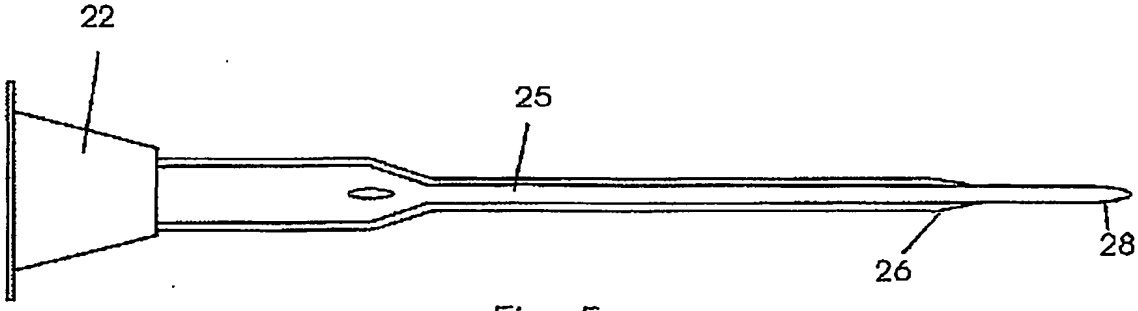


Fig. 5a

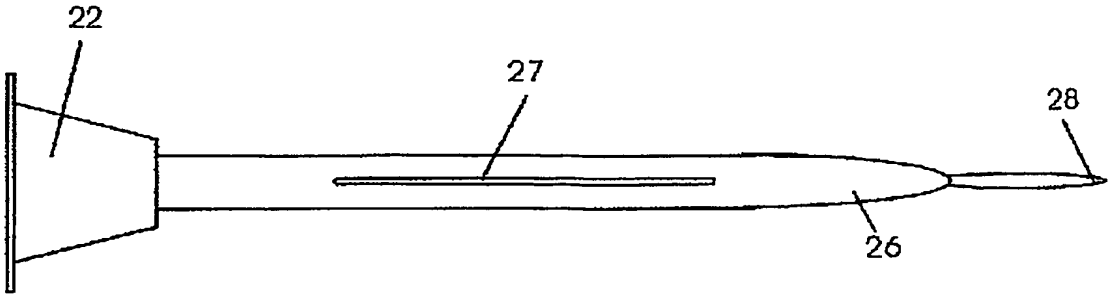


Fig. 5b

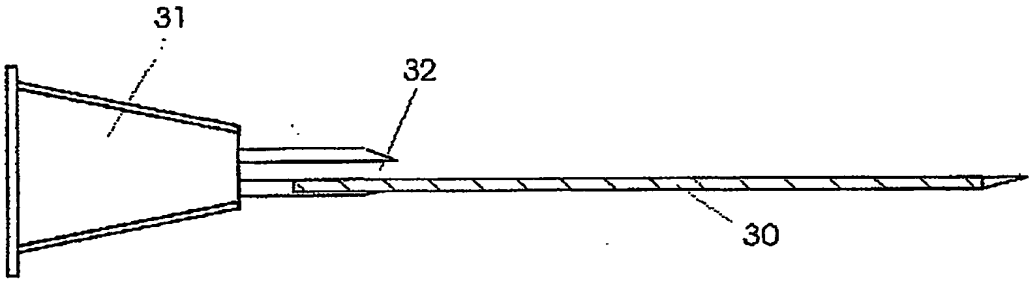


Fig. 6

Fig. 7a

Fig. 7b

Fig. 7c

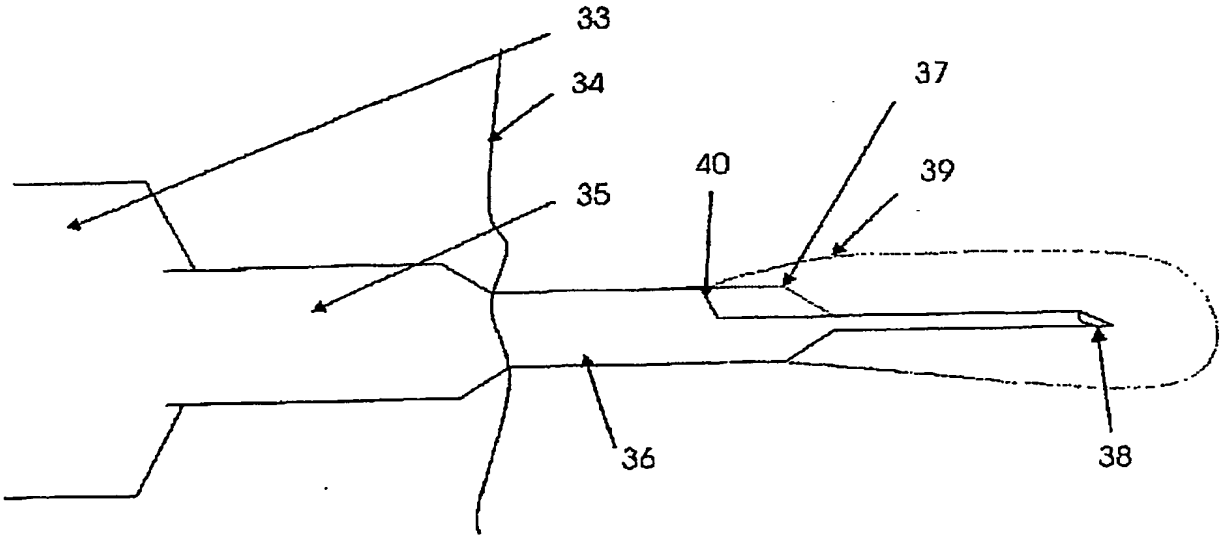


Fig. 8a

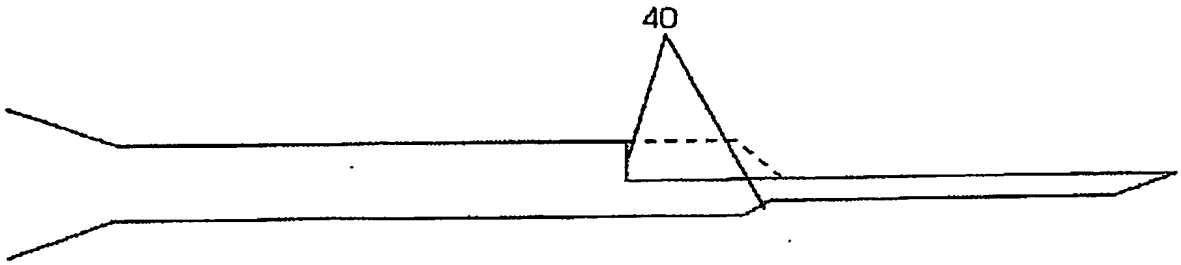


Fig. 8b

Fig. 8c

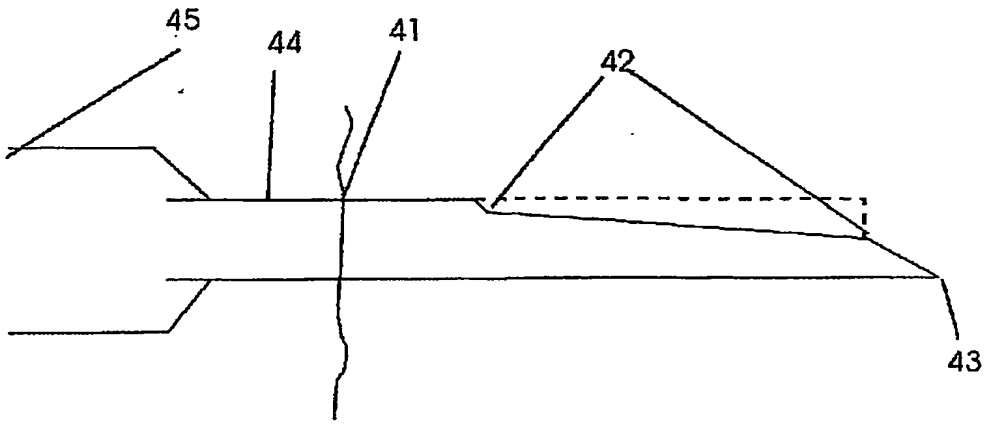


Fig. 9a

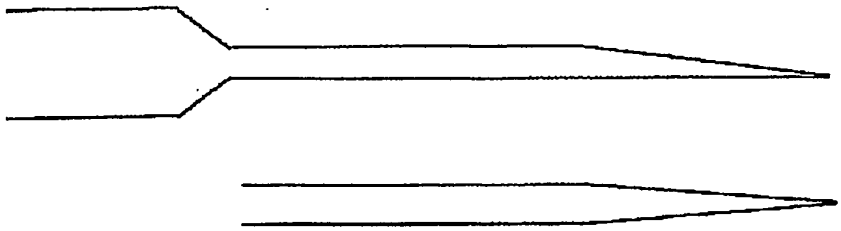


Fig. 9b

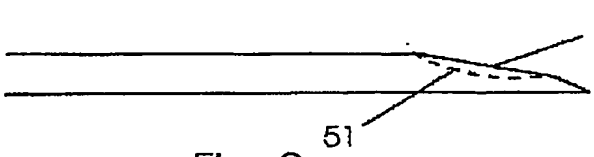


Fig. 9c

Fig. 9d

Fig. 9e

Fig. 10a

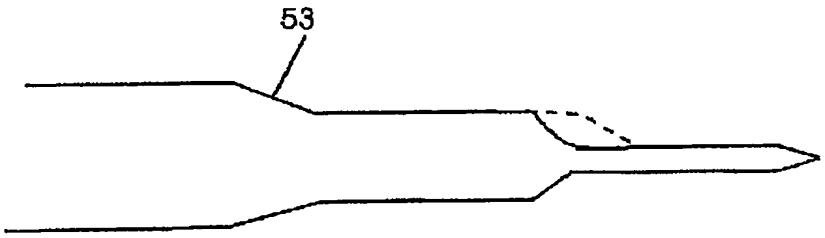


Fig. 10b

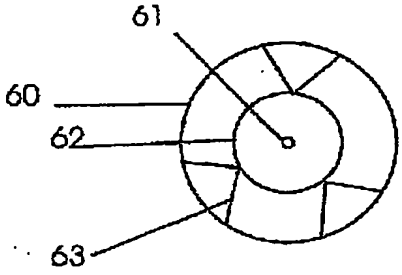


Fig. 11